REMARKS

Applicants believe that no new matter is introduced in the filing of this Preliminary Amendment. Applicants respectfully request examination of the above-named application in view of the present amendments.

Respectfully submitted,

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APPENDIX A
VERSION OF CLAIMS WITH MARKINGS

In accordance with 37 C.F.R. § 1.21(c), Applicants submit herewith a marked version of claims 54-94, in order to indicate the changes Appplicants have made to these claims.

Please delete claims 1-53 and add new claims 54-94 as follows.

-- 54. (New) A pharmaceutical composition comprising:

(i) an active agent protected in an internalized domain or pocket of an amino acid polymer wherein said amino acid polymer's structure comprises hydrophilic/polar components and hydrophobic/non-polar components designed to promote the formation of said internalized domains or pockets; and

(ii) said hydrophilic/polar components and hydrophobic/non-polar components are selected to manipulate the tertiary structure of said amino acid polymer to control degradation and release of said active agent.

55. (New) The pharmaceutical composition of claim 54, wherein said amino acid polymer is a homopolymer or heteropolymer.

56. (New) The pharmaceutical composition of claim 54, wherein said amino acid polymer further comprises amino acids selected from valine, leucine, phenylalanine, methionine, isoleucine, lysine, arginine, asparagine, glutamine, glutamic acid, tyrosine, proline, cysteine, tryptophan or derivatives thereof.

57. (New) The pharmaceutical composition of claim 54, wherein said amino acid polymer comprises at least one D-amino acid.

58. (New) The pharmaceutical composition of claim 54, wherein said length of said amino acid polymer is between 5 and 400 amino acids.

59. (New) The pharmaceutical composition of claim 54, wherein said amino acid polymer is a mixture polypeptides of varying length.

60. (New) The pharmaceutical composition of claim 54, wherein the active agent is selected from the group consisting of a nutrient, a hormone, a neurotransmitter, and a metabolic intermediate.

61. (New) The pharmaceutical composition of claim 60, wherein said active agent is selected from L-Dopa, 3-iodo-tyrosine, 3, 5-diiodo-tyrosine, L-thyroxine, glutamine, iodothyronine, aspirin, tryptophan and hydrocortisone.

62. (New) The pharmaceutical composition of claim 55, wherein said heteropolymer is a co-polymer of amino acids selected from two or more of the following: glutamic acid, phenylalanine, lysine, gamma-benzylglutamic acid, tyrosine, 3-iodo-tyrosine, 3 ,5-diiodo-tyrosine, glycine, alanine, valine, leucine, isoleucine, methionine or derivatives thereof.

63. (New) The pharmaceutical composition of claim 62, wherein said co-polymer has a molar ratio between 3 and 4.

64. (New) The pharmaceutical composition of claim 54, further comprising at least one excipient.

65. (New) The pharmaceutical composition 64, wherein said excipient is a filler, a pH buffer, an anti-oxidant, a disintegrant, a glidant, a lubricant, or a binder.

66. (New) The pharmaceutical composition of claim 56, wherein said amino acid polymer is selected from a glutamic acid polymer and a glutamic acid/tyrosine co-polymer.

67. (New) The pharmaceutical composition of claim 54, wherein said amino acid polymer is a co-polymer of lysine and phenylalanine and the active agent is hydrocortisone.

68. (New) The pharmaceutical composition of claim 54, wherein said amino acid polymer has a free energy of folding between about 3 kcal/mol and about 50 kcal/mol.

69. (New) The pharmaceutical composition of claim 54, wherein said amino acid polymer is formulated for release of a pharmaceutically effective amount of said active agent in the small intestine.

70. (New) The pharmaceutical composition of claim 54, wherein said amino acid polymer is formulated for release of a pharmaceutically effective amount of said active agent in the stomach.

71. (New) The pharmaceutical composition of claim 54, wherein said amino acid polymer is a co-polymer that consists essentially of glutamic acid and glutamine residues.

72. (New) The pharmaceutical composition of claim 54, wherein said amino acid polymer consists essentially of Cys, Pro, Glu, and Tyr residues.

73. (New) The composition of claim 1, wherein said amino acid polymer is selected from co-polymers of (1) glutamic acid and phenylalanine and (2) lysine and phenylalanine; and the active agent is L-DOPA.

74. (New) The composition of claim 1, wherein said amino acid polymer is selected from co-polymers of (1) glutamic acid and phenylalanine and (2) lysine and phenylalanine; and the active agent is aspirin.

75. (New) The pharmaceutical composition of claim 54, wherein said amino acid poly is poly-L-Lysine in helical form.

76. (New) A method of protecting a chemical compound from degradation comprising:

(i) protecting said active agent in an internalized domain or pocket of an amino acid polymer wherein the structure of said amino acid polymer comprises hydrophilic/polar components and hydrophobic/non-polar components designed to promote the formation of said internalized domains or pockets

(ii) manipulating the tertiary structure of an amino acid polymer to control degradation and release of an active agent; and

(iii) combining said active agent with said amino acid polymer.

77. (New) The method of claim 76, wherein the active agent is aspirin and said amino acid polymer is polymeric glutamic acid.

78. (New) The method of claim 76, wherein the active agent is hydrocortisone, and said amino acid polymer is a co-polymer of lysine and phenylalanine, wherein the molar ratio of Lys/Phe is between 3 and 4.

79. (New) The method of claim 76, wherein said amino acid polymer comprises a co-polymer with a molar ratio between 3 and 4.

80. (New) The method of claim 76, wherein said amino acid polymer comprises co-polymers selected from glutamic acid/phenylalanine and lysine/phenylalanine.

81. (New) The method of claim 80, wherein at least one phenylalanine is replaced by a derivative of gamma-benzylglutamic acid, tyrosine, 3-iodo-tyrosine, 3 ,5-diiodo-tyrosine, glycine, alanine, valine, leucine, isoleucine, or methionine.

82. (New) A method of treating glutamine deficiency in mammals comprising oral administration of a co-polymer consisting essentially of glutamic acid and glutamine.

83. (New) A method of treating glutamine deficiency in a cell culture comprising adding to said cell culture a nutritionally effective amount of the co-polymer consisting essentially of glutamic acid and glutamine.

84. (New) A method of treating primary adrenal insufficiency comprising administering to a patient the composition of claim 54.

85. (New) A method of treating inflammation comprising orally administering the composition of claim 54.

86. (New) A method of treating Parkinson's disease comprising orally administering the composition of claim 54.

87. (New) A cell culture serum substitute comprising a co-polymer of glutamic acid and glutamine.

88. (New) A method of producing a cysteine cross-linked polypeptide that comprises the constituent amino acids Cys, Pro, Glu, and Tyr, comprising co-polymerizing a Cys derivative, a Pro derivative, a Glu derivative, and a Tyr derivative.

89. (New) A cysteine cross-linked polypeptide that consist essentially of Cys, Pro, Glu and Tyr residues.

90. (New) A serum comprising the polypeptide of claim 89 as a synthetic serum substitute.

91. (New) A method of producing a globular polypeptide comprising co-polymerizing glutamic acid-N-carboxyanhydride (Glu-NCA) with proline-N-carboxyanhydride (Pro-NCA) in a Glu-NCA/Pro-NCA ratio greater than or equal to about 5.

92. (New) A globular polypeptide consisting essentially of Glu and Pro residues, wherein the ration of Glu/Pro is greater than or equal to 4.5.

93. (New) A method of producing a random coiled polypeptide comprising polymerizing glutamic-N-carboxyanhydride (Glu-NCA) with proline-N-carboxyanhydride (Pro-NCA) at a Glu-NCA/Pro-NCA ratio less than or equal to about 5.

94. (New) A random coiled polypeptide consisting essentially of Glu and Pro in a ratio of Glu/Pro of less than or equal to 4.5. --